

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

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ALA MOHAMAD,	*	
	*	No. 16-1075V
Petitioner,	*	Special Master Christian J.
	*	Moran
V.	*	
	*	Filed: January 27, 2022
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

* * * * *

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner;

Voris Johnson, United States Dep't of Justice, Washington, DC, for respondent.

RULING FINDING ENTITLEMENT TO COMPENSATION

Ala Mohamad alleges that a tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine caused him to develop a neurological problem known as Guillain-Barré syndrome (“GBS”). After development of written evidence, the case proceeded to a hearing. During the hearing, the parties presented testimony from experts whom they retained on various topics, including a series of publications from the Secretary about tetanus vaccines. The parties advocated for their positions in briefs submitted after the hearing.

Mr. Mohamad has carried his burden of proof. The Secretary’s documents show that a tetanus vaccine can cause GBS. This evidence plus the reports from doctors who treated Mr. Mohamad constitute preponderant evidence. Moreover, the Secretary has not established any alternative cause for Mr. Mohamad’s GBS. Accordingly, Mr. Mohamad is entitled to compensation.

I. Facts

Mr. Mohamad was born in Iraq in 1970. He was educated until the 9th grade. Tr. 16. He also received training as a machinist. Tr. 17. He immigrated to

the United States in 1999, and arrived in Colorado in 2000. Id. His wife, Salwa Asada, was born in Lebanon and came to the United States in 1997. Tr. 26.

To support his family and himself, Mr. Mohamad worked at a Winchell's Donut House, which he sold in 2012. Tr. 18. He started a grocery store called Bus Stop Groceries, which was located on Colfax Street in Denver. But, he closed the store in 2015 because business was slow. Tr. 19.

In 2015, Mr. Mohamad and his wife owned a townhouse located at Fulton Circle in Denver. Tr. 21. He testified that before the vaccination, he was in good health. Tr. 12.¹

Mr. Mohamad had an appointment with his primary care doctor, affiliated with Kaiser Permanente, to obtain a routine physical on September 18, 2015. Tr. 11; exhibit 6 at 15. During this appointment, Mr. Mohamad received the Tdap vaccination.

Mr. Mohamad returned to Kaiser on Wednesday, September 30, 2015. Exhibit 6 at 20. Kaiser provided an official interpreter to assist Mr. Mohamad. Presumably through the interpreter, Mr. Mohamad told the doctor that he had “numbness sensation in both hands and feet and lower back x 2 days.” Id.² The report of any exam is not included in the medical record. The doctor diagnosed Mr. Mohamad with hyperventilation syndrome. Id.

During the morning of the next day, Mr. Mohamad fell in his house. Exhibit 3 at 4. Mr. Mohamad was taken to the emergency department at the University of Colorado hospital. Tr. 13; exhibit 3. Mr. Mohamad informed the medical staff that he felt numbness all over his body, stating ““I feel paralyzed, like I cannot feel my body.”” Exhibit 3 at 7.³ During this appointment, Mr. Mohamad had the benefit of an official interpreter. Id. at 12.

¹ While the Secretary identified some medical conditions affecting Mr. Mohamad before the vaccination, the Secretary has not argued that any of these problems contributed to Mr. Mohamad's GBS. See Resp't's Br. at 2.

² This September 30, 2015 medical record was the primary basis for finding Mr. Mohamad developed numbness and tingling on September 28, 2015, which is 10 days after his vaccination.

³ This October 1, 2015 record states that Mr. Mohamad said his symptoms “began 4 days ago.” Four days before October 1, 2015 was September 27, 2015, making this history relatively consistent with the history from September 30, 2015.

The emergency room doctor examined Mr. Mohamad and determined that his heel-toe walk had some instability. The doctor also found Mr. Mohamad's strength and sensation were normal. Exhibit 3 at 5. The doctor diagnosed Mr. Mohamad with paresthesias of both his hands and feet. Mr. Mohamad was advised to follow-up with a neurologist and his primary care doctor. Id. at 4; Tr. 13.

The following morning, Mr. Mohamad again fell and could not get up. Exhibit 16 (affidavit) at 1. An ambulance transported Mr. Mohamad to the Medical Center of Aurora Hospital, where he remained from October 2, 2015 to October 30, 2015. Exhibit 5.2 at 601. Mr. Mohamad stated that he could not walk. Exhibit 5.1 at 254.⁴ A spinal tap revealed that Mr. Mohamad's total protein concentration in CSF was elevated, a result consistent with GBS. Id. at 258-59.

After being admitted to the hospital from the emergency room, Mr. Mohamad underwent MRIs of his spine. The MRI for his lumbar spine showed "findings [that] are compatible with GBS with smooth enhancement of the cauda equina." Exhibit 5.2 at 613. Based upon the result of the MRIs, the lumbar puncture, and the history, the doctor diagnosed Mr. Mohamad with GBS. The doctor continued: "This was likely triggered by [a] recent tetanus injection on 9/19." Id. at 614.

One of the first treatments for Mr. Mohamad's GBS was a course of IVIG given on five consecutive days from October 2 to October 6. Exhibit 5 at 614. During the IVIG treatments, Mr. Mohamad had problems breathing and was intubated from October 3 to October 9. Exhibit 5.2 at 619, 627; exhibit 5.4 at 2008.

On October 3, 2015, Dr. Heather Katz stated that Mr. Mohamad suffered from GBS "likely triggered by vaccination." Exhibit 5.3 at 830, 823.

A urine test showed that Mr. Mohamad had blood in his urine, a condition known as hematuria. He was sent for a CT scan, which showed enlargement and enhancement of both kidneys. Exhibit 5.2 at 619, 621. The internist for Mr. Mohamad, Dr. Jiang, commented that Mr. Mohamad could possibly have nephritis. Exhibit 5.3 at 808. Dr. Jiang indicated that his review of literature showed that

⁴ The history Mr. Mohamad provided about his health after the vaccination suggests that the onset of neurologic problems was earlier than September 28, 2015. See, e.g., exhibit 5.1 at 254; exhibit 5.2 at 607.

glomerulonephritis has been associated with GBS. Id. Dr. Jiang sought assistance from a nephrologist.

The nephrology service attended to Mr. Mohamad from October 17, 2015 through October 23, 2015. Exhibit 5.3 at 831-63. At the beginning of this period, one nephrologist, Dr. Villar, stated that Mr. Mohamad had “gross hematuria and mild proteinuria of unclear etiology.” Exhibit 5.3 at 862. Dr. Vallarta suggested that Mr. Mohamad might require a biopsy to reach a definitive diagnosis.

As it turns out, Mr. Mohamad did not undergo a kidney biopsy. On October 18, 2015, Dr. Vallarta assessed Mr. Mohamad’s kidney function as stable. Exhibit 5.3 at 860. In addition, Mr. Mohamad needed an additional treatment for his GBS, plasmapheresis. Thus, Dr. Vincent delayed the biopsy. Id.

Mr. Mohamad’s blood was tested for anti-streptolysin O (“ASO”) antibodies. The result was 1:1200. Exhibit 5.3 at 860/PDF 58. This result exceeded the upper limit of normal by a factor of at least 10. Tr. 138; see also Tr. 253. Based, in part, on the ASO result, Dr. Vincent stated that Mr. Mohamad’s kidney problem “could potentially be an acute post strep GN [glomerulonephritis].” Exhibit 5.3 at 860.

This note is one basis for Dr. Leist’s opinion that Mr. Mohamad suffered from a strep throat. Tr. 99-100. However, none of the doctors treating Mr. Mohamad diagnosed him as being infected with Streptococcus bacteria.

Throughout Mr. Mohamad’s stay at the Medical Center of Aurora, he was not tested for two infectious organisms that are associated with GBS, *C. jejuni* and cytomegalovirus. Tr. 98 (Dr. Leist), 278 (Dr. Halsey); see also Tr. 59 (Dr. Shafrir).

Dr. Jill Castro discharged Mr. Mohamad from the Medical Center of Aurora to a rehabilitation facility on October 30, 2015. In the discharge report, Dr. Castro stated that Mr. Mohamad had an allergy to tetanus toxoids and that the allergic reaction produced GBS. Exhibit 5.3 at 947.⁵ Dr. Castro’s linking of the tetanus vaccine to Mr. Mohamad’s GBS is consistent with an October 26, 2015 statement

⁵ The record from the Medical Center of Aurora contains multiple other notes about Mr. Mohamad's allergic reaction to the tetanus vaccine. See Exhibit 5.2 at 655, 695, 747, 752, 756, 771, 776, 781; exhibit 5.3 at 839. In addition, multiple records show that medical personnel were aware that Mr. Mohamad developed GBS “following tetanus shot.” See Exhibit 5.2 at 666, 679, 684, 691, 695-96, 701, 704, 707, 749, 753, 757, 762, 765, 769, 772, 777, 783, 791, 796, 801, Exhibit 5.3 at 809, 813, 817.

from Dr. Jeffrey Zamarripa. Dr. Zamarripa described Mr. Mohamad's chief complaint as "GBS 2/2 [secondary to] Tetanus vaccination." Exhibit 5 at 764.

After Mr. Mohamad left the Medical Center of Aurora, he had a lengthy rehabilitation and recovery. See Resp't's Br. at 5-8. But, this convalescence contributes very little, if at all, to determining whether the vaccination caused Mr. Mohamad's GBS. Tr. 74 (Dr. Shafrir), 124 (Dr. Leist); but see Tr. 272-73 (Dr. Shafrir's rebuttal testimony identifying a medical record from March 2018 indicating that Mr. Mohamad had an allergy to tetanus toxoid).

In July 2020, a neurologist (Dr. Daniel Koontz) evaluated Mr. Mohamad, who was applying for disability. Dr. Koontz determined that Mr. Mohamad's gait was slow and mildly unsteady. Dr. Koontz recommended that Mr. Mohamad should continue to take gabapentin and to increase his dose of duloxetine. Exhibit 83 at 1.

During the May 2021 hearing, Mr. Mohamad stated that he can walk, get dressed, and feed himself. His current problems include lethargy and numbness. Tr. 23; see also Tr 14. He is able to work for a friend, making donuts in a convenience store, for at least a few hours. Tr. 20. Mr. Mohamad and his wife moved from their townhouse in Denver to a house in Aurora, Colorado, which they own subject to a mortgage from a bank. Tr. 21, 28.

II. Procedural History

Mr. Mohamad initiated this action by filing a petition on August 29, 2016. Over the next six months, he filed medical records.

Mr. Mohamad disclosed some information about the extent of his possible compensation by filing a damages affidavit on February 17, 2017. Mr. Mohamad stated that before and after the vaccination his state's Medicaid program provided health care coverage. He estimated that before the vaccination he was earning approximately \$9,000 per year in income while working at Winchell's Donut House and he was starting part-time work in January 2017. Exhibit 8 (filed February 17, 2017).

After reviewing this material, the Secretary found that the record was substantially complete and invited Mr. Mohamad to consider an informal resolution. Resp't's Status Rep., filed March 14, 2017. Mr. Mohamad responded that to present a demand, his counsel would need to retain a vocational expert, an economist, and a life care planner. Pet'r's Status Rep., filed April 12, 2017.

Rather than explore settlement on these terms, the Secretary opted to defend the case. See order issued April 28, 2017.

The Secretary argued that Mr. Mohamad was not entitled to compensation for three reasons. First, the Secretary maintained that persuasive evidence did not show that a Tdap vaccination can cause GBS. For this proposition the Secretary relied upon the 2012 report from the Institute of Medicine (“IOM”), which the Secretary later submitted as exhibit B, tab 2. Second, the Secretary questioned when Mr. Mohamad began to display neurologic symptoms that were manifestations of his GBS. Third, respondent raised CIDP as a different diagnosis. Resp’t’s Report, filed June 6, 2017.

In the status conference following the submission of the Secretary’s report, Mr. Mohamad proposed that previous decisions from special masters had resolved the question that the Tdap vaccination can cause GBS or CIDP in petitioners’ favor. Accordingly, the parties were directed to file briefs on this topic. Order, issued June 21, 2017. In the status conference, Mr. Mohamad additionally announced an intention to submit a demand supported by a life care plan.

Both parties submitted briefs about precedent for Tdap vaccinations causing GBS. After reviewing these, the undersigned determined that the lack of uniformity in outcome prevented a finding in petitioner’s favor on this point before the parties had developed evidence. Order, issued August 15, 2017. The undersigned also indicated that the parties could explore settlement if they wished. Id.

Uncertainty about when Mr. Mohamad began to suffer neurologic problems appeared to be an obstacle for meaningful progress on settlement. Accordingly, the undersigned directed Mr. Mohamad to submit evidence relevant to the question of onset in advance of a hearing at which percipient witnesses could testify. Order, issued Dec. 13, 2017. During the next four months, Mr. Mohamad did not present affidavits from percipient witnesses. See order, issued March 13, 2018.

Due in part to this delay and in part to a surge in case filings, the undersigned shifted course. Instead of proceeding to an onset hearing, the undersigned directed the parties to obtain reports from experts. Order, issued May 7, 2018. Through an Order on Expert Instructions, the parties were directed to have their experts assume different dates of onset. Order, issued May 24, 2018, ¶ 6.b.ii.

Mr. Mohamad submitted his Social Security Earnings Statement on July 6, 2018. This government report showed that in the three years before vaccination, Mr. Mohamad earned \$9,175, \$13,505, and \$15,181. In 2015, the year in which Mr. Mohamad received a vaccination in September, his earnings were \$9,286. In the next year, Mr. Mohamad earned \$10,814. Exhibit 15.

Mr. Mohamad requested additional time to file a report from his expert twice and both motions were granted. Mr. Mohamad filed a third motion for enlargement of time on November 1, 2018, requesting that the report from his expert be due 45 days after a finding regarding onset. Pet'r's Mot. filed Nov. 1, 2018. This request was granted in part and denied in part. The undersigned stated that Mr. Mohamad did not require a finding regarding onset because the expert instructions presented hypothetical questions based upon different starting dates. Accordingly, Mr. Mohamad was ordered to file his expert report 45 days later. Order, issued Nov. 2, 2018.

After receiving a fourth extension of time, Mr. Mohamad submitted a report from Dr. Yuval Shafrir on February 28, 2019. Exhibit 20. Dr. Shafrir opined that a Tdap vaccination can cause GBS and that the Tdap vaccination did cause Mr. Mohamad's GBS. Id.

The Secretary responded with a report from Dr. Thomas Leist. Dr. Leist disagreed with the proposition that the Tdap vaccination can cause GBS and cited the 2012 IOM report in support. Exhibit B. Dr. Leist also maintained that a Strep infection could have caused Mr. Mohamad's GBS. Id.

Mr. Mohamad obtained a supplemental report from Dr. Shafrir. Exhibit 52, filed Sep. 10, 2019.

In the ensuing status conference, the undersigned explained that the case would not necessarily proceed to a hearing. To make sure that both parties had an opportunity to present their evidence, the undersigned scheduled another report from Dr. Leist as well as a report from Dr. Shafrir. Order, issued Oct. 15, 2019.

Without seeking any additional time, the Secretary filed a second report from Dr. Leist on November 25, 2019. Exhibit C.

Mr. Mohamad twice requested additional time to file a response from Dr. Shafrir and both requests were granted. Then, Mr. Mohamad explained that he wanted Dr. Shafrir to respond at a hearing, but not present another report. Pet'r's Status Rep., filed Feb. 26, 2020. Mr. Mohamad was reminded that a hearing was not guaranteed and given a deadline of March 12, 2020. Order, issued February

27, 2020. On the same day as this order was issued, Mr. Mohamad filed the third report from Dr. Shafrir. Exhibit 58.

It appeared that the report from Dr. Shafrir completed the submission of opinions from experts. Order, issued March 11, 2020. A comprehensive scheduling order was issued on March 25, 2020. Mr. Mohamad was directed to file updated medical records and any information regarding an application for disability benefits through the Social Security Administration by April 30, 2020. Mr. Mohamad was further instructed to file a brief regarding entitlement on May 29, 2020. The Secretary was ordered to file a response 60 days later, to which Mr. Mohamad might reply 30 days later.

To discuss the expected content of the entitlement briefs, a status conference was held on April 14, 2020. During this conference, Mr. Mohamad sought and received additional time to file his medical records, Social Security records, and employment records. The undersigned also suggested, due in part to Mr. Mohamad's relatively modest claim for lost earnings, that the parties might explore settlement. Order, issued April 14, 2020.

Later on April 14, 2020, the undersigned submitted materials from the government about the Tdap vaccine and GBS. Court exhibit 1001⁶, court exhibit 1002.⁷ The parties were offered an opportunity to obtain opinions from Dr. Shafrir and Dr. Leist about the Court exhibits. Order, issued April 14, 2020.

The Secretary sought to amend the schedule because the Secretary wished to retain a person other than Dr. Leist to address the Court exhibits. Resp't's Mot., filed April 28, 2020. Despite an objection from Mr. Mohamad, this motion was granted. Order, issued May 4, 2020. This order also set a deadline for Mr. Mohamad to file a status report regarding his presentation of a demand for settlement by June 15, 2020.

Mr. Mohamad filed exhibits on a range of topics. He submitted another report from Dr. Shafrir on May 5, 2020. Exhibit 63. He submitted updated medical records on May 20, 2020. Exhibits 72-73. He submitted his tax returns as exhibits 74-80 on May 28, 2020. Also, on May 28, 2020, Mr. Mohamad submitted a life care plan and a report from an economist. Exhibits 81-82. Mr. Mohamad

⁶ See *infra* note 22.

⁷ See *infra* note 23.

represented that he was still putting together a demand. Pet'r's Status Rep., filed June 15, 2020. He filed his initial brief regarding entitlement on June 23, 2020.

Mr. Mohamad indicated that he had not presented a demand in his July 22, 2020 status report. This deadline was then extended, sua sponte, to September 4, 2020. Order, issued August 25, 2020. However, on September 4, 2020, Mr. Mohamad did not file any status report.

The Secretary also presented evidence and argument regarding Mr. Mohamad's entitlement to compensation. On September 24, 2020, the Secretary filed another report from Dr. Leist (exhibit D), a report from Neal Halsey (exhibit E), and his initial brief.

Mr. Mohamad filed his reply brief on October 26, 2020. After reviewing the parties' evidence and their arguments, the undersigned determined that a hearing was appropriate. Order, issued January 5, 2021. The undersigned also explained that the parties may wish to explore settlement.

In conjunction with any potential efforts to resolve the case informally, Mr. Mohamad documented that the Social Security Administration found that he was disabled per the SSA rules on February 27, 2020. This document also reported that Mr. Mohamad had not reported any earnings to the SSA after 2016. Exhibit 86. This indication that Mr. Mohamad's reported earnings stopped after 2016 was consistent with the information Mr. Mohamad had filed as exhibit 15.

Mr. Mohamad indicated that he anticipated his life care plan would be finished in "mid-April." Pet'r's Status Rep., filed March 25, 2021. He filed this life care plan on April 16, 2021. Exhibit 87. With that submission, Mr. Mohamad stated that he had communicated a demand. Pet'r's Status Rep., filed April 16, 2021.

Before Mr. Mohamad filed his life care plan, the undersigned tentatively found that Mr. Mohamad's neurologic problem began on September 28, 2015. Order, issued April 12, 2021. The undersigned permitted commentary on the tentative finding of fact. Order, issued April 21, 2021. Following the pretrial conference on April 22, 2021, the tentative finding of fact became official. Ruling, issued April 23, 2021.

As for settlement, the Secretary offered a proposal on April 21, 2021. Mr. Mohamad, however, preferred to proceed to a hearing. Pet'r's Status Rep., filed April 30, 2021.

A hearing was held via videoconferencing on May 6-7, 2021. Mr. Mohamad and his wife, Salwa Asada, testified about Mr. Mohamad and his health. Mr. Mohamad called Dr. Shafrir to testify and the Secretary called Dr. Leist and Dr. Halsey as witnesses.

At the end of the hearing, Mr. Mohamad requested an opportunity to file a short brief. The undersigned outlined the significant issues, although the parties were free to address any issue that they wished. Order, issued May 12, 2021. The Secretary filed his brief on July 6, 2021, and Mr. Mohamad responded on July 27, 2021. Because the time for any reply has lapsed, Mr. Mohamad's case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence.” Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When pursuing an off-Table injury, a petitioner bears a burden “to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

The analysis consists of five parts. First, the analysis begins with an assessment of the credibility of the two original experts, Dr. Shafrir and Dr. Leist. In short, their credibility was poor. Thus, the remainder of the analysis relies upon their opinions for relatively uncontested topics. The second part addresses the most contested issue, whether a tetanus vaccine can cause GBS. The third part finds that Mr. Mohamad's GBS arose within a time for which an inference of causation is appropriate. The fourth part finds that a logical sequence of cause and effect connects the tetanus vaccine to Mr. Mohamad's GBS. The fifth and final part finds that no alternative factor caused Mr. Mohamad's GBS.

A. Evaluation of Expert's Credibility

Special masters may consider the credibility of experts who testify before them. See Moberly, 592 F.3d at 1325-26. The analysis begins with this point because the (lack of) credibility is a foundation for assessing the expert's persuasiveness. Contreras v. Sec'y of Health & Hum. Servs., 121 Fed. Cl. 230, 238 (2015) ("an expert witness who is not credible does not, as a general rule, provide reliable expert testimony"), vacated on other grounds, 844 F.3d 1363 (Fed. Cir. 2017).

To start, Dr. Shafrir's testimony revealed he has relatively little recent experience with GBS. This lack of experience tends to reduce the value of his testimony. See Copenhaver v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 176 (2016). To be sure, Dr. Shafrir is a board-certified neurologist. Tr. 31. But on the specific question about causes of GBS, his current experience is relatively slender. For a time, Dr. Shafrir taught as an attending child neurologist at Oklahoma University. However, Dr. Shafrir stopped his academic work in 2000. Exhibit 21 (curriculum vitae). More recently, he worked at Sinai Hospital, but that hospital work stopped in 2019. Tr. 31. Since his retirement from the hospital, Dr. Shafrir works at a private practice. Id. Most of Dr. Shafrir's patients are children suffering from PANDAS. Tr. 67.⁸ Dr. Shafrir most recently saw a person with GBS approximately 3-4 years ago. Tr. 68.

Apart from his relative lack of experience with GBS, portions of Dr. Shafrir's testimony reduced his credibility. On cross-examination, he sometimes evaded answering the question by providing rambling and non-responsive answers.

⁸ PANDAS is an acronym for pediatric autoimmune neuropsychiatric disorder associated with strep. Tr. 68.

See, e.g., Tr. 46, 49, 51; see also Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212 (2012) (special master may consider an expert's evasiveness in weighing an expert's testimony).

Much like Dr. Shafrir, Dr. Leist's demeanor undermined his credibility.⁹ On cross-examination, Dr. Leist attempted to parry off entirely appropriate questions. These defensive efforts left the impression that Dr. Leist either was unprepared to testify or did not want to answer questions about relevant topics. Tr. 105-15; but see Tr. 138. Special masters may consider the expert's demeanor when evaluating the strength of the testimony. See Moberly, 592 F.3d at 1325-26; Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 89 (2019) (noting special master found petitioner's expert combative and evasive); Fadelalla v. United States, 45 Fed. Cl. 196 (1999).

Dr. Leist's opinion on the role of a possible Strep infection was inconsistent. Initially, Dr. Leist's opinion was quite strong and direct: "It is my opinion that Mr. Mohamad had a streptococcal infection in late September 2015 and that this infection is the proximal cause of Mr. Mohamad's Guillaine-Barre [sic] syndrome." Exhibit B at 8. But, in his oral testimony, Dr. Leist said something different. He testified: "I'm not suggesting . . . that he had GBS because of the streptococcal infection." Tr. 133. This change in opinion was not adequately explained.

To the extent Dr. Leist even raised the possibility of a Strep infection as a possible cause of Mr. Mohamad's GBS, this position was necessarily based upon two premises. First, Mr. Mohamad was infected with Strep. Second, a Strep infection can cause GBS.

As to whether Mr. Mohamad was infected with Strep, the experts might reasonably dispute this question.¹⁰ Dr. Leist pointed to a test result showing a titer well above a normal range and the presence of protein in Mr. Mohamad's urine, a condition associated with Strep. Tr. 138-39; see also Tr. 100. Dr. Leist also relied upon the fact that some people infected with Strep do not display any symptoms.

⁹ Dr. Leist's qualifications did not raise any concerns. He is board-certified in neurology. Tr. 91-92. Dr. Leist continues working in a tertiary-level hospital where he sees patients with GBS. Tr. 91-92. Thus, strictly measured by experience with GBS, Dr. Leist was stronger than Dr. Shafrir.

¹⁰ As neurologists, neither Dr. Shafrir nor Dr. Leist carry any special qualifications in infectious diseases.

Tr. 99-101; see also exhibit D, tab 1 (Johnson et al.).¹¹ In contrast, Dr. Shafrir countered that the single positive test for anti-streptolysin O antibodies was valueless because Mr. Mohamad received IVIG before his ASO test. As such, the IVIG could have been the source of the antibodies detected on that one test. Tr. 253-55. In short, although the experts differed, they offered opinions in good faith.

However, the basis for the other supposition – that Strep can cause GBS – is questionable. To support the idea that Strep can cause GBS, Dr. Leist relies upon a case report. Exhibit B, tab 3 (Yuki).¹²

But, case reports generally offer little, if any, value in determining causation. Tr. 278 (Dr. Halsey); see also Tr. 133 (Dr. Leist). When pressed to explain why this case report was meaningful, Dr. Leist's answers were not satisfactory. Tr. 133-35. Dr. Leist's reliance upon a single case report to construct an obstacle to Mr. Mohamad's receipt of compensation is inconsistent with Dr. Leist's typical reluctance to accept case reports as evidence favoring a finding that a vaccine caused an adverse event. See Koller v. Sec'y of Health & Hum. Servs., No. 16-493V, 2021 WL 5027947, at *15 (Fed. Cl. Spec. Mstr. Oct. 8, 2021) (quoting Dr. Leist's expert report as stating “the few case reports in the literature do not provide information beyond temporality”); Harmon v. Sec'y of Health & Hum. Servs., No. 12-298V, 2017 WL 2872293, at *17 (Fed. Cl. Spec. Mstr. June 6, 2017) (quoting Dr. Leist's expert report as stating “case reports are not sufficient to establish causation”). This inconsistency, in turn, reduced Dr. Leist's overall persuasiveness. See Moberly v. Sec'y of Health & Hum. Servs., 85 Fed. Cl. 571, 606 (2009) (expert's lack of persuasiveness on one point reduced the value of the expert's testimony on other points), aff'd, 592 F.3d 1315 (Fed. Cir. 2010).

The undersigned is aware that Dr. Leist presented his opinion regarding a possible Strep infection as a possible cause for Mr. Mohamad's GBS as a secondary opinion. Exhibit C at 1; Tr. 100, 126. Dr. Leist's primary opinion is that there is a lack of persuasive evidence to support the proposition that tetanus toxoid can cause GBS. Exhibit B (report) at 4; Tr. 93-94, 104; see also Resp't's

¹¹ Dwight R. Johnson, et al., The Human Immune Response to Streptococcal Extracellular Antigens: Clinical, Diagnostic, and Potential Pathogenetic Implications, 50 CLINICAL INFECTION DISEASES 481 (2010).

¹² Nobuhiro Yuki & Koichi Hirata, Fisher's syndrome and group A streptococcal infection, 160 J. NEUROLOGICAL SCI. 64 (1998).

Br. at 14-20. The primary basis for Dr. Leist's opinion on this point is the 2012 IOM report. See exhibit C at 2.

Dr. Leist's reliance on the 2012 IOM report makes his opinion both sensible and limited. It is sensible in the sense that the IOM is comprised of knowledgeable people whose work is generally respected. Consequently, Dr. Leist's deferral to the IOM's expertise cannot really be faulted. Yet, in simply restating what the IOM said, Dr. Leist seems to be adding relatively little. See Contreras v. Sec'y of Health & Hum. Servs., 121 Fed. Cl. 230 (2015), vacated on other grounds, 844 F.3d 1363 (Fed. Cir. 2017).

Dr. Leist, for example, did not offer any testimony about how the IOM forms its conclusions or how the IOM's conclusions inform positions taken by the Secretary on these topics. The Secretary presented testimony from Dr. Halsey, whose opinions are reviewed in the following section.

B. Althen Prong 1

The first prong of Althen is equivalent to asking whether the evidence shows the vaccine can cause the injury. Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). The present case is unusual in that the most probative evidence that a tetanus-containing vaccine can cause GBS comes from statements from the Secretary. The evidence shows that the Secretary of Health and Human Services has accepted, and not rescinded, the proposition that a DTaP vaccination can cause GBS.

Acting through the Centers for Disease Control and Prevention ("CDC"), the Secretary of Health and Human Services ("HHS") has issued a series of publications that discuss, in part, a connection between a vaccine containing tetanus toxoid and GBS. An independent part of the federal government, the Institute of Medicine, has also contributed publications to this topic. These publications are reviewed in chronological order, starting with the earliest. Dr. Halsey's testimony clarified some aspects of the process through which the reports are prepared. Dr. Halsey was qualified to opine about the Secretary's process because, in part, of his earlier work as a member of the Advisory Committee on Immunization Practices ("ACIP"). The summary of the relevant government documents begins with the charter for the ACIP.

1. Charter of the Advisory Committee on Immunization Practices¹³

The Public Health Service Act, the Federal Advisory Committee Act, and the Social Security Act authorize the Secretary of Health and Human Services to appoint members to an advisory committee on immunization practices. The ACIP consists of fifteen special government employees. Exhibit E, tab 1 at 4. The Secretary of HHS selects them from authorities knowledgeable in the fields of immunization practices and public health, who have experience with the use of vaccines and other immunobiologic agents. Id. ACIP also has six non-voting ex-officio members (a detailed list is included on Exhibit E, tab 1 at 4).

The ACIP's specific duties include advising the Director of the CDC on (1) the control of diseases for which a vaccine is licensed in the United States, (2) both use of vaccines and the administration of immune globulin preparations and antimicrobial therapy, (3) vaccine administration to specific groups and populations, (4) precautions and contraindications for use of vaccines, and (5) the list of vaccines for administration to children under the Vaccines for Children Program. Id. at 2. ACIP also considers questions about disease epidemiology and burden, as they relate to vaccine efficacy and safety. Id. at 1-2. As new information about disease epidemiology and vaccine effects is published, ACIP may withdraw their recommendations regarding particular vaccines. Id. at 2.

The Director of the CDC reviews ACIP recommendations and publishes some of them as official CDC/HHS recommendations to the general public through the Morbidity and Mortality Weekly Reports ("MMWRs"). Id. at 1; Tr. 227. Dr. Halsey explained when the CDC director approves the guidance, the CDC also sends the recommendation to the Assistant Secretary of Health, who also has the authority to review the recommendations. Tr. 225-27 (discussing rescinded recommendations for health care workers to receive a vaccine against small pox).

2. 1994 ACIP General Recommendations on Immunization¹⁴

In 1994, the Secretary revised her "general recommendations" concerning vaccine practices from the previous version issued in 1989. The 1994 General

¹³ Exhibit E, tab 1: CENTER FOR DISEASE CONTROL & PREVENTION, CHARTER OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (Mar. 22, 2020), <https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf>.

¹⁴ Exhibit E, tab 4: Center for Disease Control & Prevention, General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices, 43

Recommendations provide general information about vaccines, such as vaccine storage and distribution.

The 1994 General Recommendations discussed contraindications and precautions for vaccinations. Exhibit E, tab 4 at 32. Some true contraindications and precautions include intense allergic responses and encephalopathy within seven days of receiving a vaccine.

Tetanus-toxoid vaccination is recommended for “all persons,” with the exception of individuals afflicted by serious allergic responses to previous tetanus toxoid doses. Id. at 11-12. After a serious adverse reaction to tetanus toxoid, the patient should be assessed before the administration of further doses -- generally via a dermal test for reactivity. The 1994 General Recommendations did not specifically discuss tetanus toxoid and any association with GBS.

3. 1994 IOM Publication: Adverse Events Associated with Childhood Vaccines - Evidence Bearing on Causality¹⁵

In 1994, the IOM issued a lengthy study about whether childhood vaccines can cause adverse events.

This study conducted an overview of the available medical research, as of 1994, on GBS’s relationship to receipt of tetanus toxoid-containing vaccines. Exhibit 89 at 86-89. The IOM determined the “evidence favors a causal relation between tetanus toxoid and GBS.” Id. at 89. Due to a lack of research that included a “good age-specific background rate for [GBS]”, “aggressive surveillance,” or a controlled observational study of a (preferably large) sample of participants, the IOM could not assess either the prevalence or risk of GBS-onset following tetanus toxoid-containing vaccination. Id. at 89.

The IOM concluded that tetanus toxoid-containing vaccines *can* cause GBS based on a single case study, known as the Pollard-Selby case report. Id. at 87-89. Pollard and Selby reported that a 42-year-old male laborer was found to have three episodes of GBS-onset over thirteen years, each following receipt of a tetanus-toxoid containing vaccine. The first GBS episode occurred twenty-one days after

CDC MORBIDITY & MORTALITY WKLY. REP. 1 (Jan. 28, 1994),
<https://www.cdc.gov/mmwr/PDF/rr/rr4301.pdf>.

¹⁵ Exhibit 89: INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY 86-89 (Kathleen R. Stratton, Cynthia J. Howe & Richard B. Johnston, Jr., eds., 1994).

vaccination, the second occurred fourteen days after, and the third occurred ten days after. Id. at 87. A nerve biopsy following his third episode demonstrated neuropathy consistent with GBS symptomatology: demyelination, onion bulb formation, and incipient hypertrophic neuropathy. Id. at 88. Notably, this man continued to experience multiple recurrences of demyelinating polyneuropathy following his last GBS episode, and as of 1994, was still struggling with sensory symptoms. Id. Based on the recurrent and proximate onset of GBS following the receipt of tetanus toxoid-containing vaccines, his doctors concluded that his GBS was caused by receipt of tetanus toxoid. Id. at 88-89.

The other studies that the IOM analyzed in 1994 were not so determinative. All of them were uncontrolled case studies or reports that included varying levels of detail. Id. at 87. Ultimately, the IOM found that only three of twenty-nine “GBS-diagnosis” labeled cases were detailed enough to denote GBS-onset following receipt of tetanus toxoid, and the rest either misdiagnosed GBS or were too vague. Id. For DT and Td vaccinations (which contain tetanus toxoid) specifically, the research was limited to passive reporting studies. Id. Following DT vaccination, medical reports in “the former East Germany” indicated three instances of symptomatology common to GBS from 1950-76, and the Monitoring System for Adverse Events Following Immunization listed four cases between 1979 and 1990. Id. at 88. For the Td vaccine, VAERS indicated only two “temporally associated” GBS-diagnoses. Id. It is unclear whether these reported cases for DT and Td were accurate GBS diagnoses.

Thus, the IOM concluded that GBS can be caused by tetanus toxoid vaccination, but that there is not enough reliable research to determine either prevalence or likelihood. Id. at 89.

4. 1996 Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions Recommendations of the Advisory Committee on Immunization Practices (ACIP)¹⁶

This report acted as an update (as of 1996) to the previously published ACIP recommendations pertaining to precautions, contraindications, side effects, and

¹⁶ Exhibit E, tab 3: Center for Disease Control & Prevention, Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions Recommendations of the Advisory Committee on Immunization Practices (ACIP), 45 CDC MORBIDITY & MORTALITY WKLY. REP. 1 (Sept. 6, 1996), <https://www.cdc.gov/mmwr/preview/mmwrhtml/00046738.htm>.

adverse reactions associated with vaccinations. Exhibit E, tab 3 at 1. The 1996 update compiled data from IOM findings and two ACIP MMWRs from 1993 and 1994 and highlighted major changes to the previous ACIP recommendations, particularly concerning the hepatitis B, measles, DTP, and tetanus toxoid-containing vaccines. Id. at 1. This summary focuses on the section of the report discussing tetanus toxoid-containing vaccines.

The only contraindication to tetanus (and diphtheria) toxoids is a history of a neurologic or severe hypersensitivity reaction to a previous dose. Id. at 14. Even if an anaphylactic response occurs in response to a tetanus toxoid-containing vaccination, skin testing with appropriately diluted tetanus toxoid should be used before completely discontinuing tetanus toxoid vaccination. Id. A study has shown that 94 of 95 people with a history of anaphylactic symptoms following a previous dose of tetanus toxoid were nonreactive to intradermal testing and tolerated further tetanus toxoid without incident. Id.

The 1996 Update recognized that the IOM had concluded that tetanus toxoid can trigger GBS onset, based on (1) the case study of a 42-year-old man who had GBS on three separate occasions, each following receipt of tetanus toxoid, and (2) evidence that a vaccine-induced immunologic response can cause GBS. Id. at 14.

However, this 1996 Update discussed potentially contrary evidence found in two studies. First, in a study in which over one million doses of tetanus-containing toxoid were administered to people over 18 years old, two cases of GBS were expected to appear by chance alone, and only one case was reported. Id. This indicated that risk for GBS after administration of tetanus toxoid was extremely low. Second, in a study of 0.7 million children, three cases of GBS were expected by chance alone and only two cases were reported. Id. at 13-14. Because of how rarely tetanus vaccination is associated with GBS recurrence, the decision to administer an additional tetanus toxoid-containing vaccine to a person diagnosed with GBS within six weeks should be based on the benefits of subsequent vaccination versus risk of GBS recurrence. Id. at 14.

Ultimately, in the 1996 Update, the ACIP concluded these findings suggested that the risk for GBS following administration of tetanus toxoid was “extremely low.” Id. at 14.

5. Vaccine Program Litigation

After the 1994 IOM report and the ACIP’s 1996 Update, special masters considered whether petitioners established that a tetanus-containing vaccine can

cause GBS. During this era, special masters generally found that petitioners were entitled to compensation for GBS caused by tetanus toxoid-containing vaccination. See Garcia v. Sec'y of Health and Hum. Servs., No. 05-720V, 2008 WL 5068934 (Fed. Cl. Spec. Mstr. Nov. 12, 2008) (finding entitlement for petitioner's claim that Td vaccination caused his GBS); Watson v. Sec'y of Health and Hum. Servs., No. 96-539V, 2001 U.S. Claims LEXIS 268, 2001 WL 1682537 (Fed. Cl. Spec. Mstr. Dec. 18, 2001) (ruling petitioner's GBS was caused by tetanus vaccine); Domeny v. Sec'y of Health and Hum. Servs., No. 94-1086V, 1999 U.S. Claims LEXIS 66, 1999 WL 199059, at *41 (stating "the possibility that tetanus vaccine can cause GBS is not an issue here because the court accepts that it can"). For one exception to this trend, see Tyson v. Sec'y of Health and Hum. Servs., No. 90-3379, 1997 U.S. Claims LEXIS 225, 1999 WL 702562 (Fed. Cl. Spec. Mstr. Sept. 30, 1997) (finding against entitlement because preponderant evidence did not support petitioner's claim that a tetanus toxoid-containing vaccine caused his GBS).

6. 2011 ACIP General Recommendations on Immunization¹⁷

The ACIP provided updates to its 2006 general recommendations on vaccines. As relevant for this case, the 2011 General Recommendations for the first time formally defined two terms, which had appeared in its earlier publications: "contraindication" and "precaution." A contraindication is "a condition in a recipient that increases the risk for a serious adverse reaction." Exhibit E, tab 5 at 3. A precaution is "a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity." Id. at 11.

The ACIP notes the only contraindication applicable for all vaccines (including those containing tetanus toxoid) is if the potential recipient of a vaccine suffered a severe allergic reaction, such as anaphylaxis, to a previous dose of vaccine or to a vaccine component. Id. at 11.

In the 2011 General Recommendations, the ACIP identified the following events constituted a precaution regarding a potential vaccination with tetanus toxoid: a history of Arthus-type hypersensitivity reactions after a previous dose of

¹⁷ Exhibit E, tab 5: Andrew Kroger: Center for Disease Control & Prevention, General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices, 60 CDC MORBIDITY & MORTALITY WKLY. REP. 3 (Jan. 28, 2011), <https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>.

tetanus toxoid-containing vaccine, moderate or severe acute illness with or without fever, and GBS less than six weeks after a previous dose of tetanus toxoid-containing vaccine. *Id.* at 40.

7. 2012 IOM Publication: Adverse Effects of Vaccines: Evidence and Causality¹⁸

The IOM published another report about vaccines and potential harmful consequences in 2012. Exhibit B, tab 2.¹⁹ This report underlies the position of the Secretary as well as the experts whom he retained. Resp’t’s Rep. at 9, exhibit B (Dr. Leist’s report) at 4-5, exhibit E (Dr. Halsey’s report) at 4-5.

The IOM reexamined the Pollard and Selby case report. Exhibit B, tab 2 at 559-60. After recounting the patient’s three episodes, the report notes that the authors did not rule out other possible causes (such as viral illness) and that they did not provide evidence beyond a temporal relationship to vaccine administration. *Id.* at 559-60. As such, the report concludes that the “evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and CIDP.” *Id.* at 560.

8. Litigation in the Vaccine Program after 2012 IOM

To some extent, the 2012 IOM report affected the outcome of cases in the Vaccine Program in which the Secretary appears as the respondent. See 42 U.S.C. § 300aa-12(b)(1). As noted above, previously, special masters often ruled in favor of petitioners. But, the 2012 IOM report changed the trend. For example, the special master relied heavily on the 2012 IOM report in finding that a petitioner did not establish that a tetanus-diphtheria vaccination caused her GBS. Isaac v. Sec’y of Health & Hum. Servs., No. 08-601V, 2012 WL 3609993 (Fed. Cl. Spec. Mstr. July 30, 2012), mot. for rev. denied, 108 Fed. Cl. 743, aff’d per curiam, 540

¹⁸ Exhibit B, tab 2: INSTITUTE OF MEDICINE, ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY 556-62 (Kathleen Stratton, Andrew Ford, Erin Rusch & Ellen W. Clayton, eds., 2012).

¹⁹ The IOM made available a pre-publication version of this report in 2011 and published the report in 2012. See Isaac v. Sec’y of Health & Hum. Servs., 108 Fed. Cl. 743, 754 (2013), aff’d without op., 540 Fed. App’x 999 (Fed. Cir. 2013); Raymo v. Sec’y of Health & Hum. Servs., No. 11-0654V, 2014 WL 1092274, at *3 n.11 (Fed. Cl. Spec. Mstr. Feb. 24, 2014). This ruling refers to the report as the “2012 IOM report.”

Fed. App'x 999 (Fed. Cir. 2013).²⁰ Other examples include Tompkins v. Sec'y of Health and Hum. Servs., No. 10-261V, 2013 WL 3498652, *24 (Fed. Cl. Spec. Mstr. June 21, 2013) (concluding that “the evidence that tetanus vaccine can cause GBS is lacking.”), mot. for rev. denied, 117 Fed. Cl. 713 (2014) and Rupert v. Sec'y of Health and Hum. Servs., No. 10-160V, 2014 WL 785256 (Fed. Cl. Spec. Mstr. Feb. 3, 2014) (finding petitioner failed to establish by preponderant evidence that Tdap vaccine caused his GBS, and respondent proved upper respiratory tract infection as sole cause of the GBS).

While the special masters found Ms. Isaac, Mr. Tompkins, and Mr. Rupert were not entitled to compensation, other petitioners asserting that a vaccine with tetanus toxoid caused their GBS did receive compensation. Mr. Mohamad listed multiple cases in which the Secretary resolved a case in which a petitioner alleged a vaccine containing tetanus toxoid caused GBS. In these cases, the Secretary compensated the petitioner without admitting that the vaccine caused the GBS. Pet'r's Br., filed June 23, 2020, appendix III.²¹

9. 2018 ACIP Publication: Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices²²

Jennifer Liang et al. compiled the recommendations from ACIP “regarding prevention and control of tetanus, diphtheria, and pertussis” in the United States, in order to provide clinicians and public health providers with a comprehensive and up-to-date “resource.” Court Exhibit 1001 at 4. The review discusses the DTaP, Tdap, and Td vaccinations, as well as their component parts -- acellular pertussis, and diphtheria and tetanus toxoids.

DTaP contains diphtheria and tetanus toxoids with acellular pertussis; Tdap, as a booster, contains tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; and Td, also a booster, contains reduced tetanus toxoid and reduced

²⁰ The Secretary cited Isaac and other cases in his July 21, 2017 memorandum and in his September 24, 2020 memorandum.

²¹ The Secretary did not address these settled cases in his September 24, 2020 memorandum. An expanded version of this list is attached to this ruling as an appendix.

²² Exhibit 1001: Center for Disease Control & Prevention, Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 67 CDC MORBIDITY & MORTALITY WKLY. REP. 1 (Apr. 27, 2018), <https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf>.

diphtheria toxoid. DTaP administration typically occurs in five rounds between six weeks and six years old; Tdap is administered once during adolescence (and to adult women during pregnancy); and Td is administered every ten years throughout life.

DTaP, Tdap, and Td, like many vaccinations, have certain contraindications and precautions. The ACIP explains that a contraindication is a “condition in a recipient that increases the risk for a serious adverse reaction,” and medical professionals should not administer vaccinations when one (or more) is present. Id. at 33. Precautions, by contrast, do not always justify vaccine deferral -- these conditions are often mistaken for contraindications, but are not as serious. Thus, their negative effects can sometimes be outweighed by the benefits of a vaccine. Id. Because DTaP, Tdap, and Td consist of two to three components, the contraindications and precautions associated with each specific component also apply to DTaP, Tdap, and Td administration. Id. at 22, 33.

ACIP recommends that GBS occurring less than six weeks after receipt of a tetanus toxoid-containing vaccine is a precaution for subsequent administration of tetanus toxoid-containing vaccines. Notably, however, reports of GBS (and other severe neurologic reactions) following receipt of a tetanus toxoid-containing vaccine (TT, DTaP, Tdap, Td) are very rare. Id. at 22-23. The ACIP also cites the 2012 IOM publication, that “the evidence was inadequate to accept or reject a causal relation between receipt of diphtheria toxoid- and tetanus toxoid-containing vaccines and . . . Guillain Barré syndrome, . . .” Id. at 23.

10. General Best Practice Guidelines for Immunization - Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) (2019)²³

This report is separated into ten documents, which outline updates accepted by ACIP as of October 2014. Court Exhibit 1002 at 6. These updates regard recommendations for seventeen vaccine-preventable diseases, and they are based on studies and reviews conducted by medical professionals belonging to the General Recommendations Working Group (“GRWG”) and Immunization Action Coalition. Id. at 3, 6. Ezeanalue et al. compiled these updates to provide a guideline for clinicians who vaccinate patients in various healthcare settings. Id. at

²³ Exhibit 1002: Echezona Ezeanalue, et al., General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (2019).

3. One major general update was made to the term “precaution” -- its definition has been “enhanced” to include any condition that might confuse diagnostic accuracy. Id. at 4. The report also specifically addresses updates made to recommendations for tetanus toxoid-containing vaccines, which will be the rest of this summary’s focus.

After monthly meetings in 2013, the GRWG revised the “Preventing and Managing Adverse Reactions” recommendations to explain that certain vaccinations, like Td (adult tetanus and diphtheria toxoids) and DT (pediatric diphtheria and tetanus toxoids), produce increased rates of local or systemic reactions in certain recipients when administered more frequently than recommended. Id. at 14. It stressed the importance of “careful record keeping, maintenance of patient histories, and use of immunization information” to prevent such unnecessary reactions. Id. at 14-15.

Additionally, Table 4.1 explicitly details the updated list of contraindications and precautions for the DT, Td, Tdap, and DTaP vaccinations. Id. at 53. For Td and DT, there is only one contraindication: severe allergic reaction, e.g. anaphylaxis, after a previous dose or to a vaccine component, e.g. tetanus toxoid. The precautions include: GBS less than six weeks after a previous dose of tetanus toxoid-containing vaccine, history of hypersensitivity reactions after a previous dose of diphtheria toxoid- or tetanus toxoid-containing vaccines, and/or moderate or severe acute illness following a previous dose or component (with or without fever). Id. For individuals with an Arthus-type hypersensitivity history, clinicians should defer vaccination until at least ten years post-initial tetanus toxoid-containing vaccine receipt. Id.

For both DTaP and Tdap, the contraindications are: severe allergic reactions and encephalopathy, not attributable to some other cause, within seven days of previous dose of DTP or DTaP. Id. at 53, 57. The precautions are the same as for DT and Td, with the addition of “progressive neurologic disorders,” like epilepsy and progressive encephalopathy. Prior to administration, neurologic disorders of these kinds should first be evaluated by a physician. Id.

11. Testimony about these Documents

Of the three testifying doctors, Dr. Halsey provided the most useful testimony about how the Secretary communicates information about vaccinations, including any concerns for adverse consequences, to the public. While Dr. Shafrir and Dr. Leist talked about some of the documents, their knowledge seemed to extend only to reading the documents. See Tr. 35-39, 51-52 (Dr. Shafrir), 93-95

(Dr. Leist), 259-66 (Dr. Shafrir's rebuttal testimony). Dr. Halsey, on the other hand, had insights into the process leading to the production of the documents. But, even Dr. Halsey's knowledge was limited once he stopped participating in working groups and Dr. Halsey filled some of the gaps in his first-hand knowledge by speculating. See Tr. 174-76.²⁴

The thrust of Dr. Halsey's opinion is that the Pollard & Selby case report was misunderstood originally, the IOM corrected that misunderstanding in 2012, and the Secretary has overlooked the 2012 IOM change. Tr. 156-61. Thus, to Dr. Halsey, the recommendations found in the ACIP's 2019 Best Practice Guidelines are misguided. However, Dr. Halsey's opinion is not persuasive.

To start, the IOM's 2012 report did change its previous assessment, but not as drastically as sometimes suggested. In its 1994 report, the IOM found a vaccine containing tetanus-toxoid can cause GBS. This finding was based upon an understanding that the subject of the Pollard & Selby case report experienced neurologic symptoms attributable to GBS when he first received the tetanus vaccine and experienced neurologic symptoms when he again received the tetanus vaccine. This pattern of recurrence is known as "challenge-rechallenge" and evidence of "challenge-rechallenge" can demonstrate that an exposure is causing an adverse reaction. See Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1322 (Fed. Cir. 2006) (defining rechallenge).

However, by 2011, additional information about the subject of the Pollard & Selby report was learned. He experienced neurologic problems at times not in association with a tetanus vaccine. His doctors, therefore, determined that he suffered from a different disease, chronic inflammatory demyelinating polyneuropathy. Tr. 94-95. With this information in hand, the IOM retreated from its previous conclusion that a tetanus vaccine can cause GBS. Tr. 157. In 2012, the IOM determined that the evidence "is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines and GBS." Exhibit B, tab 2 at 558. As Dr. Halsey explained, this conclusion was "neutral," and the IOM did not go the extra step of saying that the evidence "favors rejection." Tr. 238-39. In Dr. Halsey's view, this shift did not attract much attention. Tr. 222.

²⁴ The Secretary might have avoided presenting speculation if the Secretary had called an employee within the Department of Health and Human Services who actually participated in the meetings.

To Dr. Halsey, the critical step is what happened (or more precisely, what failed to happen) after the 2012 IOM report. Dr. Halsey maintains that people on the ACIP did not consider modifying the recommendation regarding GBS. Tr. 161, 240.

Dr. Halsey's assertion is difficult to accept for three reasons. First, the ACIP divides tasks among working groups and the meetings of working groups are closed to the public. Tr. 243. Thus, it appears that Dr. Halsey did not participate in the working group that led to the 2019 Best Practice Guidance. So, an assertion that the ACIP did not consider the 2012 IOM shift is more an assumption than a preponderantly supported fact.

Next, the 2018 ACIP recommendations refers to the 2012 IOM report. See Tr. 170. Thus, Dr. Halsey cannot say and has not suggested that the members of the ACIP were entirely ignorant of the 2012 IOM report. Instead, Dr. Halsey surmises that the ACIP failed to appreciate the significance of the 2012 IOM change.

These points lead to the third point making Dr. Halsey's position unconvincing. Dr. Halsey seems to be calling into question the professionalism of the members of the ACIP, essentially saying that the members were asleep at the switch. Tr. 174-75. However, members of the ACIP are selected for their knowledge in the field of vaccines, vaccine effectiveness, and vaccine safety. Tr. 239. For example, one member of the ACIP is the director of the Health Resources and Services Administration ("HRSA"). Tr. 228. In that capacity, Dr. Nair signed stipulations in which the Secretary of HHS agreed to pay people who alleged a tetanus vaccine caused their GBS. See Vaccine Rule 11(b) ("Any stipulation for a money judgment must be signed by authorized representatives of the Secretary of Health and Human Services and the Attorney General"). Dr. Nair's personal participation in the settlement of these cases strongly suggests that he was aware that tetanus-GBS cases are litigated in the Vaccine Program.²⁵ As a member of the

²⁵ Each stipulation duly notes that the Secretary has not admitted that the tetanus vaccine causes GBS. See e.g., Woodward v. Sec'y of Health & Hum. Servs., No. 15-1130V, 2017 WL 1239864 (Fed. Cl. Spec. Mstr. Mar. 9, 2017). As such, the stipulations do not serve as admissions. See Woods v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 148, 152-53 (2012) (noting Federal Rules of Evidence policy regarding settlement offers not reflecting admission of liability). However, stipulations / settlements can constitute notice of a problem. See Spell v. McDaniel, 824 F.2d 1380 (4th Cir. 1987) (finding prior settlement by the city of a brutality claim was properly admitted to prove that the city was on notice of problem of aggressive police officers in a subsequent civil rights case alleging excessive force by an officer); Abundis v. United States, 15 Cl. Ct. 619, 621 (1988) ("There is an exception to application of [Federal] Rule

Department of Health and Human Services on the ACIP, Dr. Nair had an opportunity to change the Secretary's communications about any causal relationship between tetanus vaccine and GBS.

12. Interpretation of the Secretary's Most Recent Statement

In 2019, the Secretary offered guidance to the American public, including practicing doctors, about the best practices for vaccines. The Secretary maintained that a previous occurrence of GBS within six weeks of a tetanus vaccine warranted a "precaution." Tr. 174, 242. A precaution, in turn, means "a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity." Exhibit E, tab 5 at 11. To borrow from the 1996 General Recommendations, there is a "low risk" that a tetanus vaccine can cause GBS. See Tr. 232.

Dr. Halsey wished that the Secretary had used different words. Tr. 232-34. But, the Secretary is responsible for the words appearing in documents for which he is responsible. The process by which the Secretary released the 2019 Best Practices involves multiple steps in which many talented people participate. The undersigned sees no persuasive reason to edit the 2019 Best Practices.

The 2019 Best Practices, which comes from the Secretary, constitutes strong evidence that a tetanus vaccine can cause GBS in rare cases. This evidence is sufficiently robust that it carries petitioner's burden with respect to general causation.

The 2019 Best Practices outweighs the value of the opinions from Dr. Leist and Dr. Halsey. Dr. Leist's opinion carries relatively less weight because Dr. Leist's analysis of the issue seems to start and to stop with the 2012 IOM report. See exhibit B at 4-6; Tr. 93-95. While Dr. Leist is correct that the 2012 IOM report did not accept the theory that a tetanus vaccine can cause GBS, the IOM report also did not reject the proposition entirely.²⁶

Dr. Halsey's experience on the safety of vaccines is greater than Dr. Leist's experience. Thus, the undersigned does not dismiss Dr. Halsey's opinion as readily. Dr. Halsey indicated that there is no persuasive evidence that a tetanus

[of Evidence] 408, however, when the evidence of settlement is not offered to prove liability or damages, but for some other purpose.").

²⁶ See INSTITUTE OF MEDICINE, *supra* note 18, at 558.

vaccine can cause GBS. Tr. 153-55. Part of Dr. Halsey's assessment of the evidence, however, included a conclusion that the 2019 Best Practices document reflects an "oversight." Tr. 174-75. For the reasons explained above, the undersigned does not share Dr. Halsey's conclusion on this point.

Special masters are not required to deny compensation when the IOM takes a neutral stance. See Estep v. Sec'y of Health & Hum. Servs., 28 Fed. Cl. 664, 668 (1993) ("The [Vaccine] Act does not require [a special master] to accept the IOM Report as dispositive"), app. dismissed, No. 93-5192 (Fed. Cir. Oct. 29, 1993); Raymo v. Sec'y of Health & Hum. Servs., No. 11-0654V, 2014 WL 1092274, at *21 (Fed. Cl. Feb. 24, 2014) ("it is apparent that the IOM requires a very high standard before concluding that there is a causal relationship between vaccines and an injury").

Because the Secretary acknowledged the low risk that in rare cases a tetanus vaccine can cause GBS by making a prior occurrence of GBS in temporal relationship with a tetanus vaccine a precaution, Mr. Mohamad is not required to establish, with preponderant evidence, the precise theory by which a tetanus vaccine can cause GBS. See Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 549 (Fed. Cir. 1994) ("to require identification and proof of specific biologic mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program"). The Secretary did not require elucidation of a scientific theory in 1996 when the ACIP concluded that there was some (albeit "extremely low") risk for GBS following administration of tetanus toxoid.

Mr. Mohamad cannot be expected to bear a higher burden than the Secretary in his public pronouncements. Accordingly, the evidence preponderates in favor of finding that Mr. Mohamad has met his Althen prong one burden.²⁷

C. Althen prong 3

Having found that a tetanus vaccine can cause GBS, the undersigned next turns to the question of when GBS would typically manifest after the vaccine if the vaccine caused the GBS. Dr. Shafrir analogized the process by which a tetanus vaccine can cause GBS to the process by which flu vaccine can cause GBS. Tr.

²⁷ If Dr. Halsey's prediction that the ACIP revises the Secretary's guidance comes true, then the evidence will be different. The parties might also present different evidence in the form of testimony from immunologists, epidemiologists, and/or people with first-hand knowledge of the creation of the 2019 Best Practices. Different evidence in any hypothetical future case might produce a different result.

40. Because the Secretary's Vaccine Injury Table establishes a presumption that causation is appropriate when GBS develops 3-42 days after the flu vaccine, 42 C.F.R. § 100.3(a) ¶ XIV.D., Dr. Shafrir maintained that an onset of GBS within this period would be appropriate. Id.

Based upon the medical records, as well as the expert's commentary on that evidence, the undersigned found that Mr. Mohamad's numbness started on September 28, 2015, ten days after vaccination. Ruling Finding Fact, issued Apr. 23, 2021. The experts recognized that Mr. Mohamad's numbness marked the beginning of his GBS. Tr. 40 (Dr. Shafrir), 104 (Dr. Leist acknowledging a temporal relationship).

Accordingly, Mr. Mohamad has established that his GBS was manifest within a time for which an inference of causation is appropriate. He has satisfied Althen prong 3.

D. Althen prong 2

In determining whether petitioners have met the second prong of Althen, the Federal Circuit has emphasized the value of statements of treating doctors.

If a claimant satisfies the first and third prongs of the Althen standard, the second prong can be met through medical opinion testimony. Such testimony is "quite probative" since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury."

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009) (quoting Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006)).

Here, as Dr. Shafrir and Dr. Leist recognized, different doctors treating Mr. Mohamad linked the preceding tetanus vaccine to his GBS. Some examples from the Medical Center of Aurora Hospital follow.

On October 2, 2015, Dr. Dennis Keselman assessed Mr. Mohamad's injury "was likely triggered by recent tetanus injection," and Dr. Kenneth Tompkins, Jr. listed "Tetanus Vaccines & Toxoid" as coded allergies. Exhibit 5.2 at 614. The record from Mr. Mohamad's assessment by Dr. Janice Brenneman and Dr. Heather Katz on October 3, 2015 notes his GBS was "[l]ikely triggered by vaccination."

Exhibit 5.3 at 830. This conclusion was repeated on October 4, 2015. Id. at 823. On October 26, 2015, Dr. Jeffrey Zamarripa noted the subjective chief complaint as “GBS 2/2 Tetanus vaccination.” Exhibit 5.2 at 764. The same notation was repeated the following day by Dr. Zamarripa. Id. at 759.

These statements implicate the vaccine directly and explicitly. They are, therefore, more probative than various statements in which medical personnel mentioned a temporal sequence in which the vaccine preceded the disease. For a list of examples, see Pet'r's Br., filed June 23, 2020, at 3-5. Mr. Mohamad's treating doctors' statements that a tetanus vaccine caused his GBS also imply that a tetanus vaccine can cause GBS generally. As such, these statements from treating doctors are also relevant to the prong 1 discussion above. See Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 136-37 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012).

Dr. Shafrir relied, in part, on the treating doctor's statements to support his opinion that the tetanus vaccine did cause Mr. Mohamad's GBS. Tr. 41, 64. Although Dr. Leist recognized these statements, he disagreed with them because, in part, the treating doctors did not explain their reasoning. Tr. 97-98. Dr. Leist also noted that the doctors did not explore whether Mr. Mohamad had any conditions commonly suspected as causes for GBS, such as *C. jejuni*. Tr. 107. Dr. Halsey shared this concern as well. Tr. 244, 278.

The lack of testing does not prevent Mr. Mohamad from meeting his burden of proof, which is merely preponderant evidence, not evidence beyond a reasonable doubt. The evidence from the treating doctors carries Mr. Mohamad's burden regarding Althen prong 2.

E. Alternative Cause

Because Mr. Mohamad has met his burden of establishing that the vaccine was the cause-in-fact of his GBS, the burden shifts to the Secretary to present an alternative cause. See LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014). Here, it appears that the Secretary may have offered a possible Strep infection as a cause for Mr. Mohamad's GBS. However, for the reasons discussed in section IV.A above, Dr. Leist's opinion on this topic was not credible. Accordingly, a preponderance of the evidence does not support a finding that any Strep infection was an alternative cause.

V. Conclusion

Mr. Mohamad has established that he is entitled to compensation. An order to guide the parties in their assessment of damages will follow.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

List of Tdap – GBS Cases Settled by HHS

Docket #	Westlaw Citation	Date	SM	HHS Official	Primary Amount	Medicaid Liens	Medical Expenses	Other
12-246V	2012 WL 6176760	11/16/2012	Moran	Caserta, Vito	\$135,000.00			\$13,500.00 (AF&C)
11-864V	2013 WL 474300	1/16/2013	Vowell	Caserta, Vito	\$150,000.00			
12-141V	2013 WL 4476837	7/18/2013	Zane	Caserta, Vito	\$305,000.00			
11-437V	2013 WL 4479852	7/24/2013	Zane	Caserta, Vito	\$237,500.00			
12-277V	2014 WL 1689953	4/8/2014	Hamilton-Fieldman	Caserta, Vito	\$125,000.00	\$66,633.55		
13-351V	2014 WL 3884448	7/14/2014	Hamilton-Fieldman	Houston, Melissa	\$125,000.00			
13-589V	2015 WL 324651	1/5/2015	Millman	Houston, Melissa	\$218,000.00			
14-209V	2015 WL 477204	1/13/2015	Millman	Houston, Melissa	\$100,000.00			
12-276V	2015 WL 1805515	3/26/2015	Corcoran	Houston, Melissa	\$290,000.00	\$2,907.67		
14-99V	2015 WL 1932239	4/6/2015	Gowen	Houston, Melissa	\$105,000.00			
13-1019V	2015 WL 2195111	4/15/2015	Moran	Houston, Melissa	\$100,000.00			
14-882V	2015 WL 2453389	4/29/2015	Vowell	Houston, Melissa	\$110,000.00			
10-522V	2015 WL 4734740	7/17/2015	Millman	Houston, Melissa	\$60,000.00			
14-840V	2015 WL 5499318	8/21/2015	Hamilton-Fieldman	Houston, Melissa	\$129,385.20	\$443.69		
13-104V	2015 WL 6395694	9/11/2015	Gowen	Houston, Melissa	\$280,015.62			Annuity
14-363V	2015 WL 8521058	11/12/2015	Gowen	Houston, Melissa	\$525,000.00			
14-1188V	2015 WL 10434887	12/1/2015	Corcoran	Houston, Melissa	\$200,000.00			
15-567V	2015 WL 9700586	12/10/2015	Gowen	Houston, Melissa	\$137,500.00			
13-628V	2015 WL 9595427	12/11/2015	Hamilton-Fieldman	Houston, Melissa	\$290,000.00			
15-509V	2016 WL 943839	2/19/2016	Moran	NA	\$145,000.00			
14-127V	2016 WL 1560074	3/24/2016	Moran	Nair, Narayan	\$165,000.00			
15-001V	2016 WL 1567116	3/25/2016	Moran	Nair, Narayan	\$140,000.00			
13-944V	2016 WL 2641400	4/14/2016	Hamilton-Fieldman	NA	\$750,000.00			
13-337V	2016 WL 8114125	6/17/2016	Gowen	Nair, Narayan	\$400,000.00			
15-1164V	2016 WL 5867277	8/5/2016	Dorsey	Nair, Narayan	\$132,500.00			
14-336V	2016 WL 6839549	10/12/2016	Hamilton-Fieldman	Nair, Narayan	\$215,006.21	\$121,210.21		
16-156V	2016 WL 6806275	10/13/2016	Corcoran	Nair, Narayan	\$190,000.00			

List of Tdap – GBS Cases Settled by HHS

15-568V	2016 WL 7488354	11/10/2016	Corcoran	Nair, Narayan	\$155,000.00			
16-169V	2017 WL 436105	1/3/2017	Corcoran	Nair, Narayan	\$84,464.00			
16-274V	2017 WL 514247	1/12/2017	Gowen	Nair, Narayan	\$160,000.00			
15-1130V	2017 WL 1239864	3/9/2017	Gowen	Nair, Narayan	\$345,000.00			
16-74V	2017 WL 4324984	3/10/2017	Dorsey	Nair, Narayan	\$150,000.00			
16-894V	2017 WL 1424051	3/27/2017	Roth	Nair, Narayan	\$132,718.94			
16-846V	2017 WL 1737714	4/5/2017	Corcoran	Nair, Narayan	\$150,000.00			
16-1069V	2017 WL 1737716	4/6/2017	Gowen	Nair, Narayan	\$140,000.00			
14-1224V	2017 WL 2116705	4/20/2017	Roth	Nair, Narayan	\$90,000.00			
16-562V	2017 WL 2418308	5/11/2017	Roth	Nair, Narayan	\$140,000.00			
16-822V	2017 WL 2812933	5/22/2017	Gowen	Nair, Narayan	\$200,000.00			
16-1005V	2017 WL 3574915	6/28/2017	Corcoran	Nair, Narayan	\$150,000.00			
16-06V	2017 WL 3445253	7/17/2017	Roth	Nair, Narayan	\$150,000.00			
15-1099V	2017 WL 3623558	7/27/2017	Gowen	Nair, Narayan	\$120,000.00			
12-124V	2017 WL 4174072	8/23/2017	Gowen	Nair, Narayan	\$850,000.00			
16-725V	2018 WL 615074	1/2/2018	Moran	Nair, Narayan	\$235,000.00			
16-375V	2018 WL 818262	1/16/2018	Roth	Nair, Narayan	\$440,000.00	\$2,809.18		
17-648V	2018 WL 2225991	3/29/2018	Corcoran	Nair, Narayan	\$142,000.00			
16-15V	2018 WL 3030970	5/17/2018	Moran	Nair, Narayan	\$130,000.00			
16-868V	2018 WL 3991064	6/27/2018	Moran	Nair, Narayan	\$80,000.00			
14-880V	2018 WL 3989449	7/13/2018	Moran	Nair, Narayan	\$118,000.00			
16-641V	2018 WL 4042363	7/30/2018	Roth	Nair, Narayan	\$132,500.00			
16-1228V	2018 WL 6975188	11/15/2018	Corcoran	Nair, Narayan	\$80,000.00			
17-1135V	2018 WL 6582356	11/19/2018	Roth	Nair, Narayan	\$81,650.77			
17-883V	2019 WL 1451311	2/11/2019	Corcoran	Nair, Narayan	\$115,000.00			
17-1963V	2019 WL 1283779	2/22/2019	Roth	Nair, Narayan	\$82,500.00			
17-819V	2019 WL 6358958	9/27/2019	Corcoran	Overby, Tamara	\$150,000.00	\$1,870.41		

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16-598V	2019 WL 5889230	10/18/2019	Gowen	Overby, Tamara	\$25,000.00			
17-1184V	2020 WL 995975	2/6/2020	Roth	Overby, Tamara	\$147,500.00		\$12,459.65	
18-622V	2020 WL 1429238	2/27/2020	Gowen	Overby, Tamara	\$155,000.00			
18-1372V	2020 WL 3839891	6/3/2020	Oler	Overby, Tamara	\$77,500.00			
19-523V	2020 WL 6303764	9/11/2020	Roth	Overby, Tamara	\$200,000.00			
18-1317V	2020 WL 6146045	9/23/2020	Moran	Overby, Tamara	\$107,000.00			
15-713V	2020 WL 6043838	9/23/2020	Gowen	Overby, Tamara	\$170,000.00			
18-1067V	2020 WL 6636353	10/16/2020	Roth	Overby, Tamara	\$93,322.98			
19-267V	2020 WL 7093975	10/28/2020	Oler	Overby, Tamara	\$117,500.00			
17-1063V	2020 WL 6940012	10/29/2020	Moran	Overby, Tamara	\$22,500.00			
19-223V	2021 WL 619683	1/26/2021	Gowen	Overby, Tamara	\$60,000.00			
18-1420V	2021 WL 1352262	2/23/2021	Oler	Overby, Tamara	\$132,265.99		\$14,713.53	
19-546V	2021 WL 1120974	3/2/2021	Moran	Overby, Tamara	\$40,400.00			
18-1796V	2021 WL 1346043	3/16/2021	Roth	Overby, Tamara	\$105,000.00			
17-174V	2021 WL 2795423	3/23/2021	Moran	Overby, Tamara	\$654,253.29	\$86,235.24		Annuity
16-521V	2021 WL 2206519	5/4/2021	Moran	Overby, Tamara	\$32,120.59	\$7,879.41		
20-392V	2021 WL 2310429	5/12/2021	Roth	Overby, Tamara	\$60,000.00			
19-980V	2021 WL 2805297	6/8/2021	Roth	Overby, Tamara	\$120,000.00			
20-767V	2021 WL 3206105	6/15/2021	Oler	Overby, Tamara	\$105,000.00			
20-915V	2021 WL 4305860	8/24/2021	Horner	Overby, Tamara	\$103,315.74			
18-1211V	2021 WL 5851062	9/22/2021	Oler	Overby, Tamara	\$20,000.00			
20-1036V	2021 WL 4955867	10/5/2021	Gowen	Overby, Tamara	\$47,500.00	\$10,000.00		
19-1283V	2021 WL 5567538	11/2/2021	Horner	Overby, Tamara	\$135,181.05			